BACKGROUNDER

Regulation phasing out ozone-depleting sterilants

A draft regulation was released on June 29, 1994 for a 30-day public comment period by Environment and Energy Minister Bud Wildman. The regulation would phase out the discharge, manufacture, use or transfer of specific Class 1, CFC-based ozone-depleting sterilants and ultimately prohibit storage of these materials.

The regulation also sets phaseout deadlines for Class 2 chemicals, the less damaging hydrochlorofluorocarbons (HCFC) which have been developed as interim materials for use during the CFC phaseout.

The draft regulation:

- Prohibits the discharge of specific Class 1 and Class 2 ozone-depleting substances used as a sterilant after January 1, 1996 and 2000 respectively.
- Prohibits making, using or transferring these Class 1 and Class 2 ozone-depleting substances as of January 1, 1996 and 2000 respectively.
- Prohibits the storage of Class 1 and Class 2 ozone-depleting substances used as a sterilant after 1998 and 2002 respectively.
- Requires a report for Class 1 sterilants stored after 1996 and Class 2 sterilants stored after 2000 to be available on request by the Ministry of Environment and Energy.
- Exempts Class 1 and 2 sterilants used for research purposes related to the study of the ozone layer.
- Exempts use where the Class 1 and 2 sterilants used in a process are converted to another substance which is not an Class 1 or 2 sterilant.
- Exempts use where the Class 1 or 2 sterilants are created and then converted to another substance which is not a Class 1 or 2 sterilant.
- This regulation overrides conditions included in existing certificates of approval for Class 1 and 2 sterilants.

Background

Ozone-depleting substances (ODS) cause serious environmental and health problems. They destroy the ozone layer that protects us from ultraviolet (UV-B) radiation and they contribute to the global warming effect. UV-B radiation causes skin cancer, cataracts, crop and material damage.

Among ODS, CFC-12 is used as a diluent of ethylene oxide for the purpose of sterilization of medical devices in hospitals.

Canada has signed the Montreal Protocol which bans the production and import of ODS, including CFCs, by January 1, 1996. Since CFCs are not produced in Canada, they will not be available after the phaseout date. Unlike the federal regulations, Ontario legislation will regulate the use of specified Class 1 and 2 ozone-depleting substances used as sterilants and sets a phaseout schedule for sterilants that complements the Montreal Protocol.

Furthermore, discharge/emissions of sterilants into the environment and limitations of their storage will be prohibited, making the Ontario regulation the most comprehensive legislation in Canada.

With this regulation, Ontario will be the first province to set up a specific schedule for phasing out HCFCs which were designated as transitional substances.

Industry information

CFC-12 is not produced in Canada nor is sterilant equipment. The mixture 12/88 is a blend of 12 per cent ethylene oxide (ETO) and 88 per cent CFC-12. Medical facilities use 12/88 to sterilize medical instruments and equipment such as respiratory equipment, diagnostic instruments and fibre optics.

"Blender" firms, which blend CFC-12 with ethylene oxide to make 12/88, are found in Ontario.

Approximately 120 tonnes of CFCs were used in Ontario last year for sterilization, or 3.4 per cent of total CFC usage. Users of sterilants include hospitals (which account for almost 98 per cent of the total number of sterilizers in the province), pharmaceutical companies, private and provincial medical labs and a veterinary hospital in Guelph. There are approximately 360 CFC-12/ETO sterilizer units in Ontario hospitals.

Alternatives

Alternative sterilizing gases and technologies that can be used instead of the 12/88 gas mixture include:

- Low-temperature Gas Plasma Sterilization
- Low-temperature Gas Plasma Sterilization using hydrogen peroxide, H_2O_2
- Low-temperature Sterilization unit using Peracetic acid
- Low-temperature vapour phase sterilization unit using H_2O_2
- Low-temperature sterilization unit using 100 per cent ethylene oxide gas cartridges
- A system which removes ETO from the air stream exhausted from Steri-Vac Sterilizer
- Use of 10 per cent ETO/90 per cent CO_2 gas mixtures, 100 per cent ETO or HCFC-124 with integrated ETO removal from exhaust
- Gamma Sterilization
- Ultraviolet Radiation

The phaseout is expected to result in upgraded sterilization systems in Ontario hospitals. As well, the development of a "green" industry may result as producers invest in the new market. This technology change presents a potential export opportunity for Ontario.

Changing to cost-effective technologies may bring about savings in sterilization costs. In addition, some alternatives present reduced danger of explosions or adverse health effects from continued use of toxic and cancer-causing ethylene oxide.

Public comment on the proposed regulation must be mailed or delivered by August 2, 1994 to:

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